K012455

AUG 1 7 2001

II. 510(k) Summary

[As described in CFR 807.92]

Submitted by: Welch Allyn Inc.
95 Old Shoals Road
Arden, NC 28704

Contact Person: David A. Young II
Quality Assurance Engineer

Date Prepared: 15 January 2001

Proprietary Name: Welch Allyn® DuraShock™ Blood Pressure System

Common Name: Blood Pressure Sphygmomanometer

Classification Name: Class II 870.1120 Blood Pressure Cuff

Predicate Device: Welch Allyn, Tycos® Econo Blood Pressure Sphygmomanometer
Welch Allyn, Inc.
510(k) Document Control Number *NA (predicate device is a pre-amendment device)*

Description of the Device:

The Welch Allyn® DuraShock™ Blood Pressure System is a non-invasive blood pressure (BP) measurement device. The DuraShock™ Blood Pressure System is designed to non-invasively measure systolic and diastolic blood pressure for adult and pediatric patients. The Welch Allyn® DuraShock™ Blood Pressure System consists of five components, DuraShock™ Gauge, Integrated One Piece Cuff, Bulb, Valve, and Tubing. The DuraShock™ Blood Pressure System comes in two models. Model ds44 is a lower cost unit with a 5 year warranty, while model ds45 is a higher cost unit that carries a 10 year warranty. Each model will be available in four cuff sizes, Large Adult, Adult, Small Adult, and Child which conform to AAMI SP-9, and AHA. The DuraShock™ Gauge is revolutionary, in that in place of a gear driven movement as found in traditional aneroids, the NCA spring driven movement will be utilized, providing the user with a more durable aneroid. The NCA spring driven movement as opposed to using gears, diaphragm travel is converted to pointer rotation by using a spring wrapped around a pin. The DuraShock™ system also features a Integrated one piece cuff with integral bladder that contains a port where the DuraShock™ Gauge can be directly inserted into the bladder of the cuff. This point of attachment of gauge

to cuff, will make it more convenient for use, as well as making it easier for the clinician to read. By attaching directly to the bladder, this will allow the clinician to read the gauge without holding it, thus freeing up their hands to hold the stethoscope head, and bulb and valve to inflate the cuff. The DuraShock™ model ds45 configurations, will utilize a black neoprene bulb, metal valve, and black TPR tubing that is currently being used on the Welch Allyn Tycos® Econo Blood Pressure System. On DuraShock™ model ds44 configurations, a plastic valve, gray PVC bulb and gray TPR tubing will be used.

The Welch Allyn® DuraShock™ Blood Pressure System is intended for use in a wide variety of settings. This includes hospital departments, alternate care settings, such as physician offices, freestanding ambulatory care and surgery centers, health clinics and nursing homes, as well as home health care.

Indications/Contraindications For Use of the Device:

The Welch Allyn® DuraShock™ Blood Pressure System has the same intended use as the predicate device. The device is intended for the non-invasive blood pressure measurements of adult and pediatric patients. The device is not designed, sold or intended for use except as indicated.

The Welch Allyn® DuraShock™ Blood Pressure System is not designed for use with neonates. To ensure pediatric blood pressure accuracy and safety, note that the Welch Allyn® DuraShock™ Child cuff is the smallest cuff approved for use with DuraShock™ aneroid on children and infants. For the DuraShock™ Blood Pressure System to accurately determine blood pressure, the circumference of the child or infant's arm must fit within the range markings on the cuff.

Technological Characteristics:

The Welch Allyn® DuraShock™ Blood Pressure System differs from the predicate device, in that it utilizes the NCA spring movement in place of the traditional gear driven movement. The DuraShock™ Blood Pressure System also utilizes a Integrated one piece cuff that has a port in which the DuraShock™ gauge can be inserted directly into the bladder of the cuff. The predicate device utilizes a hose port, and length of black TPR tubing to attach the gauge to the cuff. The same black neoprene manual bulb, valve, and black TPR tubing will be utilized on the DuraShock™ model ds45 that is currently used on the predicate device, while model ds44 will use a plastic valve, gray PVC bulb and gray TPR tubing will be used. The following table summarizes the similarities and differences between the Welch Allyn® DuraShock™ Blood Pressure System and the Welch Allyn Tycos® Econo Blood Pressure System.

Table 1

Specifications & Technological Comparison Between the Welch Allyn® DuraShock™ Blood Pressure System and the Welch Allyn Tycos® Econo Blood Pressure System.

	Welch Allyn® DuraShock™ Blood Pressure System Model ds45	**Welch Allyn® DuraShock™ Blood Pressure System Model ds44**	**Welch Allyn, Tycos® Econo Blood Pressure System.**
Blood Pressure			
BP Determination Method	Non-invasive	Non-invasive	Non-invasive
Initial Cuff Inflation	Operator dependent capable of inflation to 300 mmHg.	Operator dependent capable of inflation to 300 mmHg.	Operator dependent capable of inflation to 300 mmHg.
Inflation/Deflation	Black Neoprene Manual Bulb, Metal Valve, & Black TPR Tubing	Gray PVC Manual Bulb, Plastic Valve, & Gray TPR Tubing	Black Neoprene Manual Bulb, Metal Valve, & Black TPR Tubing
Movement			
	Spring Driven	Spring Driven	Gear Driven
Measurement Range			
Systolic	20-300 mmHg	20-300 mmHg	20-300 mmHg
Diastolic	20-300 mmHg	20-300 mmHg	20-300 mmHg
Measurement Accuracy			
Cuff Pressure	+/- 3 mmHg	+/- 3 mmHg	+/- 3 mmHg
Blood Pressure	AAMI SP9-1994	AAMI SP9-1994	AAMI SP9-1994
Measurement time (sec.)	30-60 sec. Typical	30-60 sec. Typical	30-60 sec. Typical
Overall System			
Patient Population	Pediatric/Adult	Pediatric/Adult	Pediatric/Adult
Display Type	Dial	Dial	Dial
Warranty	Ten Years	Five Years	Ten Years
DuraShock™ Gauge:			
Length	2.1 inches (5.33 cm)	2.1 inches (5.33 cm)	3.75 inches (9.525 cm)
Width	2.1 inches (5.33 cm)	2.1 inches (5.33 cm)	2.35 inches (5.97 cm)
Height	0.85 inches (2.16 cm)	0.85 inches (2.16 cm)	1.25 inches (3.18 cm)
Weight	0.10 lb. (45.36 g)	0.10 lb. (45.36 g)	0.35 lb. (158.76 g)
Protective Bumper	Yes (Black & Gray)	Yes (Multi-Color)	No
Cuff:	Durable Integrated One Piece with DuraShock™ Port	Durable Integrated One Piece with DuraShock™ Port	One Piece Cuff with no DuraShock™ Port
Cuff Sizes	Lg. Adult, Adult, Sm.	Lg. Adult, Adult, Sm.	Thigh, Lg. Adult,

(Available)	Adult, Child	Adult, Child	Adult, Sm. Adult, Child, Sm. Child, Infant, Newborn
Point of Attachment	Inserted Directly into Bladder Section of Cuff	Inserted Directly into Bladder Section of Cuff	Attaches to Hose Port of Cuff via Length of TPR/PVC Tubing
Operating Conditions			
Operating Temperature	0 to 46 °C	0 to 46 °C	0 to 46 C
Humidity Range	0 to 85% RH non-condensing	0 to 85% RH non-condensing	0 to 85% RH non-condensing
Storage Temperature	-34 to 70 °C	-34 to 70 °C	-34 to 70 °C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 7 2001

Mr. David A. Young II
Quality Assurance engineer
Welch Allyn, Inc.
95 Old Shoals Road
Arden, NC 28704

Re: K012455
Device Name: DuraShock Blood Pressure System
Regulation Number: 870.1120
Regulatory Class: Class II (two)
Product Code: DXQ
Dated: July 9, 2001
Received: August 1, 2001

Dear Mr. Young:

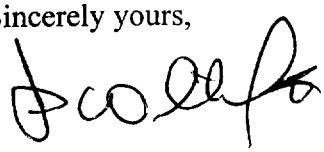
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

VII. Indications for Use Statement

510(k) Number: Unknown

Device Name: Welch Allyn® DuraShock™ Blood Pressure System

Indications for use: The DuraShock™ Blood Pressure System ~~is~~ intended for the non-invasive blood pressure measurement of adult and pediatric patients. The device is not designed, sold or intended for use except as indicated. *The Welch Allyn® DuraShock™ Blood Pressure System is not designed for use with neonates.* To ensure pediatric blood pressure accuracy and safety, note that the Welch Allyn® DuraShock™ child is the smallest cuff approved for use with children and infants whose arm circumference fit within the range markings on the cuff.

(Please Do Not Write Below This Line - Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ Or Over-The-Counter Use ✓

(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012455